

In re: Odidi et al.
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Remarks/Arguments

Claims 1, 6-9, 11, 15-17 and 21-34 remain in this application. Claims 1, 17, 23, 31 and 33 have been amended to correct a clerical error and to further define that the encasement coat is non-permeable, as supported, for instance, at page 3, paragraph [36] of the description.

Claims 11, 15, 16, 22, 24, 25, 27-29, and 34

Applicant respectfully notes that the Examiner did not reject the subject matter recited in Claims 11, 15, 16, 22, 24, 25, 27-29, and 34. As such, Applicant respectfully submits that Claims 11, 15, 16, 22, 24, 25, 27-29, and 34 are objected to for depending upon a rejected base claim but would be allowable if rewritten in independent form to include all of the subject matter recited in the appropriate basic claim as well as any corresponding intervening claims.

Specification Objection-35 U.S.C. §132

Previous amendments to the specification at paragraphs [38] and [40] have been objected to by the Examiner. The Examiner asserts that the added material, "extrusion aid may be microcrystalline cellulose", is not supported by the original specification. It is respectfully submitted that one of skill in the art would readily understand what an extrusion aid is and what type of material would be suitable as an extrusion aid. In particular, it is well known in the prior art that microcrystalline cellulose is an extrusion aid (see U.S. Patents 4,980,062; 4,180,411 and 4,976,846). As mentioned in the previous amendment, microcrystalline cellulose was inadvertently listed as a compression aid in the specification and should have been referred to as an extrusion aid. This inadvertent error would have been recognized by one of ordinary skill in the art prior to the filing date and priority date of the present application, as noted in the previously presented U.S. patents. Consequently, Applicant submits that no new matter has been added to the specification.

Claim Rejections - 35 U.S.C. § 103(a)

Claims 1, 6-9, 17, 21, 23, 26 and 30-33 are rejected under 35 U.S.C. § 103 as being unpatentable over Cheng.

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The Examiner asserts that the claimed invention is "open to Cheng's polymers since instant claims do not specifically name polymers." The Applicant respectfully disagrees with the Examiner. Applicant submits that it is not necessary to specifically name the polymers since the encasement coat of the claimed invention has been fully defined in terms of its' properties. The claimed invention is directed to a formulation comprising an encasement coat that is non-permeable and soluble at a pH of above about 5.0. Therefore, in order to achieve such a non-permeable encasement coating soluble at a pH of above about 5.0, the chosen polymer must provide an encasement coating having these specific properties, which is clearly distinguishable from Cheng's polymers.

The Examiner further asserts that the "instant claims do not state whether the polymers are non-enteric or enteric". The Applicant asserts that it is not necessary to further define the polymers of the claimed invention as enteric since the chosen polymer of the claimed invention must provide an encasement coating that is non-permeable and soluble at a pH of above about 5.0, which is clearly distinguishable from Cheng's polymers.

As recited in the previous Amendment, Cheng teaches a core of active that is coated with a semi-permeable membrane. The semi-permeable membrane is stated to be permeable to the passage of an external fluid such as water and biological fluids and is impermeable to the passage of the drug in the core (column 4, lines 10-16). As such, the semi-permeable membrane does not dissolve but rather remains intact at alkaline pH and during transit in the gastrointestinal tract. It is stated in column 4 of Cheng that the materials useful in forming the semi-permeable membrane are "cellulose esters, cellulose diesters,...The most preferred semi-permeable membrane material cellulose acetate comprising an acetyl content of 39.3 to 40.3%". As indicated in the excerpt from Eastman Chemical Company 1995, submitted with the previous amendment, cellulose esters may be enteric or non-enteric. Non-enteric cellulose esters are semi-permeable and are represented, for example, by cellulose acetate which is the preferred polymer taught by Cheng.

It is submitted that the claimed invention is directed to a formulation comprising an encasement coat that is non-permeable and soluble at a pH of above about 5.0. Therefore, in order to achieve such a non-permeable encasement coating soluble at a pH of above about 5.0,

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the chosen polymer must provide an encasement coating having these specific properties. Hence, one skilled in the art, in view of the description and the claimed invention, would choose only polymers that would have such properties. Cheng does not teach or suggest polymers that would provide an encasement coating having the specific properties of the claimed invention. Applicant submits, therefore, that the claimed invention does not encompass the polymers of Cheng, which are semi-permeable and not soluble at a pH of above about 5.0.

The Examiner further asserts that "Cheng discloses that the semi permeable membrane is formed from 50-90% polymers (cellulose acetate), PEG, and plasticizer which are also acceptable components of the instant claims. For this reason, it would have been obvious to expect the prior art invention (semi permeable membrane) to be soluble at a pH above 5.0". The Applicant respectfully disagrees with the Examiner. It is respectfully submitted that the Examiner incorrectly concludes that the polymers of Cheng are also acceptable components of the formulation of the claimed invention. The polymers of Cheng would not provide an encasement coating that is non-permeable and soluble at a pH of above about 5.0. Applicants submit a declaration attached herewith showing pH studies conducted with respect to cellulose acetate and anionic polymers of methacrylic acid and methacrylates (e.g. Eudragit L). As is exhibited in Schedule A of the declaration, cellulose acetate is not soluble above pH 5.0 and anionic polymers of methacrylic acid and methacrylates (e.g. Eudragit L), which are examples of suitable polymers for the encasement coat of the claimed invention, are soluble above pH of 5.0. Consequently, cellulose acetate, as taught by Cheng, is not a suitable polymer for the encasement coat of the claimed invention. Furthermore, the polymers suggested by Cheng are semi-permeable and would, therefore, not be suitable for the non-permeable encasement coat of the claimed invention.

The Examiner also asserts that "Cheng teaches an encasement coat comprising a polymer film (cellulose acetate) encasing an active wherein the coat comprises 50-90% polymer and 0-25% PEG". The Examiner further asserts that "Cheng's amount of PEG overlaps the amount of PEG disclosed by the instant invention. It is very possible that the optimum amount of PEG could fall at a point that is within both the prior art and instant invention range." The Examiner also asserts that "although the instant invention teaches 50-90% polymer and the instant invention

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teaches less than 50% polymer, the Applicant does not show unexpected data for Cheng's coating having 49% polymer". As fully discussed above, Cheng does not teach or suggest polymers that would provide the encasement coat of the claimed invention, wherein the encasement coat is non-permeable and soluble at a pH of above about 5.0. It is further respectfully submitted that, in view of this distinction, the percentage ranges of the polymer of the claimed invention are irrelevant.

To establish *prima facie* obviousness of a rejected claim, the applied art of record must teach or suggest each and every feature of a rejected claim. See M.P.E.P. §2143.03. As explained above, Cheng fails to teach or suggest each and every feature of rejected Claims 1, 6-9, 17, 21, 23, 26 and 30-33; an encasement coat that is non-permeable and soluble at a pH of above about 5.0.

Moreover, to establish *prima facie* obviousness, there must also be some suggestion or motivation, either in the applied reference or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. See M.P.E.P. §2143 and §2143.01. As mentioned above, Cheng teaches a core of active that is coated with a semi-permeable membrane. The semi-permeable membrane is stated to be permeable to the passage of an external fluid such as water and biological fluids and is impermeable to the passage of the drug in the core (column 4, lines 10-16). Cheng does not provide any motivation to use a polymer that would provide a non-permeable encasement coat, let alone an encasement coat that is soluble at a pH of above about 5.0.

Therefore, Applicant respectfully submits that Claims 1, 6-9, 17, 21, 23, 26 and 30-33 are not rendered obvious in view of the applied teaching of Cheng and should be deemed allowable. As such, Applicant respectfully requests withdrawal of the rejections.

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Conclusion

In view of the foregoing, reconsideration of the application, withdrawal of the outstanding rejections, allowance of Claims 1, 6-9, 11, 15-17, 21-34, and the prompt issuance of a Notice of Allowability are respectfully solicited.

Respectfully submitted,

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